

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Bioterrorism Agent Notification Procedures

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How well do you know the notification procedure you should use in the event that you are faced with a suspected biological terrorism (BT) agent? Do you know who to contact and when you should contact them? If you do, then you are one step closer to being fully prepared to deal with such an event. If you don't know what to do, and even if you do, take a minute to review the following procedures, and then add the telephone numbers for your facility to the box on page 4 and place a copy with your laboratory protocols. Be sure that your lab staff knows where these protocols are located and review them on a regular basis, updating information as needed.

Bioterrorism agents include viruses, bacteria, fungi, or toxins from living organisms that are used to produce death or disease in humans, animals, or plants. Many of these diseases can present with nonspecific symptoms. The following situations could represent a possible BT event and should be reported immediately to the local health department or local health jurisdiction (LHJ):

- A single diagnosed or strongly suspected case of disease caused by an uncommon agent or a potential agent of bioterrorism occurring in a patient with no known risk factors;
- A cluster of patients presenting with a similar syndrome that includes unusual disease characteristics or unusually high morbidity or mortality without obvious etiology; or
- Unexplained increase in a common syndrome above seasonally expected levels.

Sentinel laboratories (laboratories that perform blood and/or CSF cultures) will, in many instances, be the first to encounter suspect agents. If a sentinel laboratory or a clinical assessment comes up with findings that are suggestive of a BT agent, there are several things that should be done. Having the following procedures in place and using the attached notification template, you'll help ensure a timely and efficient response to the appearance of a suspect, unknown biological agent:

- Ensure that the specimen is collected utilizing proper procedures.
- Follow approved protocols for transportation, storage, and handling of the sample.
- Preserve and secure the original specimen.
- Know what paperwork is required for referrals and be sure you know what information is needed on that paperwork.

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	PAP Smear
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness
Lipid Screening	

BT Agent Notification Procedures, continued from page 1

As a sentinel laboratory, your primary job when dealing with a suspected agent is to “rule out or refer.” See the Centers for Disease Control and Prevention (CDC) website at <http://www.bt.cdc.gov/lrn/> for additional information about the National Laboratory Response Network (LRN).

Any event that involves a suspected BT agent must be reported to the appropriate authorities immediately. The laboratory technologist should alert the microbiology supervisor if a suspect organism is isolated. Once the supervisor has confirmed the technologist’s findings, the supervisor should then contact the laboratory director, who should be accessible via a phone number that is available 24 hours a day, 7 days a week. Once notified, the laboratory director or designee is responsible to inform the attending physician or the patient’s physician; the local or regional hospital infection control and the infectious disease service, if that service is available for the area; and the LHJ of the patient’s residence.

It is the LHJ’s responsibility to contact the Washington State Department of Health (DOH) Communicable Diseases Epidemiology staff of the laboratory findings. Once the DOH has been notified, they will contact the DOH Public Health Laboratories, another LRN Reference Laboratory (Level B lab), the CDC, or the FBI, as appropriate. Should an actual BT event occur, all of these agencies will become involved. Should that happen,

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Website addresses:

DOH home page: <http://www.doh.wa.gov>
LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

particularly if law enforcement becomes involved, be aware that your laboratory bears the burden of proving that the specimen was received, handled, and processed by authorized laboratory personnel.

The LHJ may request that a specimen be submitted for further testing by a LRN Reference Laboratory. The following information must be provided:

- Specimen type
- Name and telephone number of the laboratory
- Date that the specimen was collected
- Date the specimen was received
- Requesting health care provider’s name and telephone number or address
- Test result
- Name of the patient (if available) or a patient identifier along with the sex and date of birth or age of the patient (if available).

If additional testing is required, the LHJ will advise the sentinel laboratory to which LRN Reference Laboratory the specimen should be sent, how it should be sent, and any special packaging and shipping instructions. The LHJ will also ensure that any positive results from additional testing are reported back to the patient’s physician and the originating laboratory.

Useful posters that list notifiable conditions, including BT agents, can be found at the Washington State Department of Health’s website at <http://www.doh.wa.gov/notify>. If you need to report a specific disease, the DOH maintains a website at <http://www.doh.wa.gov/notify/forms/> with disease-specific reporting forms that can be printed out as needed. The DOH Clinical Laboratory Advisory Council’s “Suspected BT Event Management Guideline” can be found on pages 4-5 and at the following website: http://www.doh.wa.gov/hsqa/fsl/lqa_practice_guidelines.htm.

By being aware of and by following these procedures, not only will you expedite the process of dealing with a suspect BT agent or environmental sample, but you will also help ensure that the specimen or sample is handled correctly from the time it enters your laboratory to the time you pass it on for further testing. Your performance as a sentinel laboratory can make a critical difference in how a biological event or chemical incident is managed and contained by those agencies that respond to your alarm.

Portions of this article were obtained from the *Washington State Guidelines for Notifiable Condition Reporting and Surveillance*, found at the following url: <http://www.doh.wa.gov/Notify/guidelines/pdf/ngc20021014.pdf>

continued on pages 4-5

12th Annual Clinical Laboratory Conference

by Leonard Kargacin, DOH LQA

The 12th Annual Clinical Laboratory Conference will be held on November 7, 2005 at the Seattle Marriott Hotel near Sea-Tac International Airport. This is an excellent opportunity to hear about the current status of health care from a variety of experts.

Dennis Weissman, President of Dennis Weissman & Associates, LLC in Washington, D.C. will present the Keynote address for the Conference. This year's session is titled **"Washington Alert for Labs: Key National Developments and Trends for Today and the Future"**. Those who have heard Dennis speak in the past know that his presentation will be very dynamic and thought provoking.

What's New in Laboratory Regulation and the Inspection Process: This portion of the program will briefly review some of the changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations in 2003-2004. Lori Hudson from the Washington State Department of Health Medical Test Site (MTS) Licensing Program, Steve Sarewitz, MD, Checklist Commissioner from the College of American Pathologists (CAP), and Kathy Steffens, Associate Director of Laboratory Accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will participate. Each presenter will highlight how the changes in the CLIA regulations are being implemented into their programs, discuss other changes, and new directions/trends concerning their respective programs. There will be time for questions.

Current Trends in Laboratory Management: Health care organizations from the small physician office to the large hospitals, clinics, and medical centers are often challenged to improve quality and expand service without the addition of new resources or new space. This portion of the program will review the latest trends in laboratory design and management techniques: Rapid Process Improvement (RPI) and Lean Management Principles. Whereas Lean management principles are generally being applied in larger health care systems, the RPI process can be applied anywhere from the small physician office or clinic to large hospitals and medical centers. Joanne Simpson, Laboratory Director at Children's Hospital and Regional Medical Center, and Lee Darrow, Laboratory Administrative Director at Virginia Mason Medical Center in Seattle will discuss the implementation of Lean principles in their facilities in a case study format. Anna Franklin, Quality Assurance Manager at Pathology Associates Medical Laboratories in Spokane, will review the RPI process and discuss how it can be applied in facilities of all sizes. There will be ample time for questions from the audience.

WHO SHOULD ATTEND?

- Laboratory Directors
- Laboratory / Office Managers
- Department Supervisors
- Bench Personnel
- Billing Personnel
- Compliance Officers

The Conference offers something pertinent for everyone whether you work in a physician office laboratory, an independent laboratory, or a small or large hospital.

LOCATION

The Conference will be held at the Seattle Marriott Hotel at Sea-Tac Airport with easy access from Interstate 5 and the airport. Conference programs and registration information was mailed in mid-September. The registration fee will be \$95.00 per person and will include a continental breakfast, breaks and lunch.

If you have not received your Conference Registration Flyer, the program is available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm

MAKE YOUR PLANS TO ATTEND TODAY!!

CLINICAL LABORATORY SUSPECTED BIOTERRORISM (BT) EVENT MANAGEMENT GUIDELINE

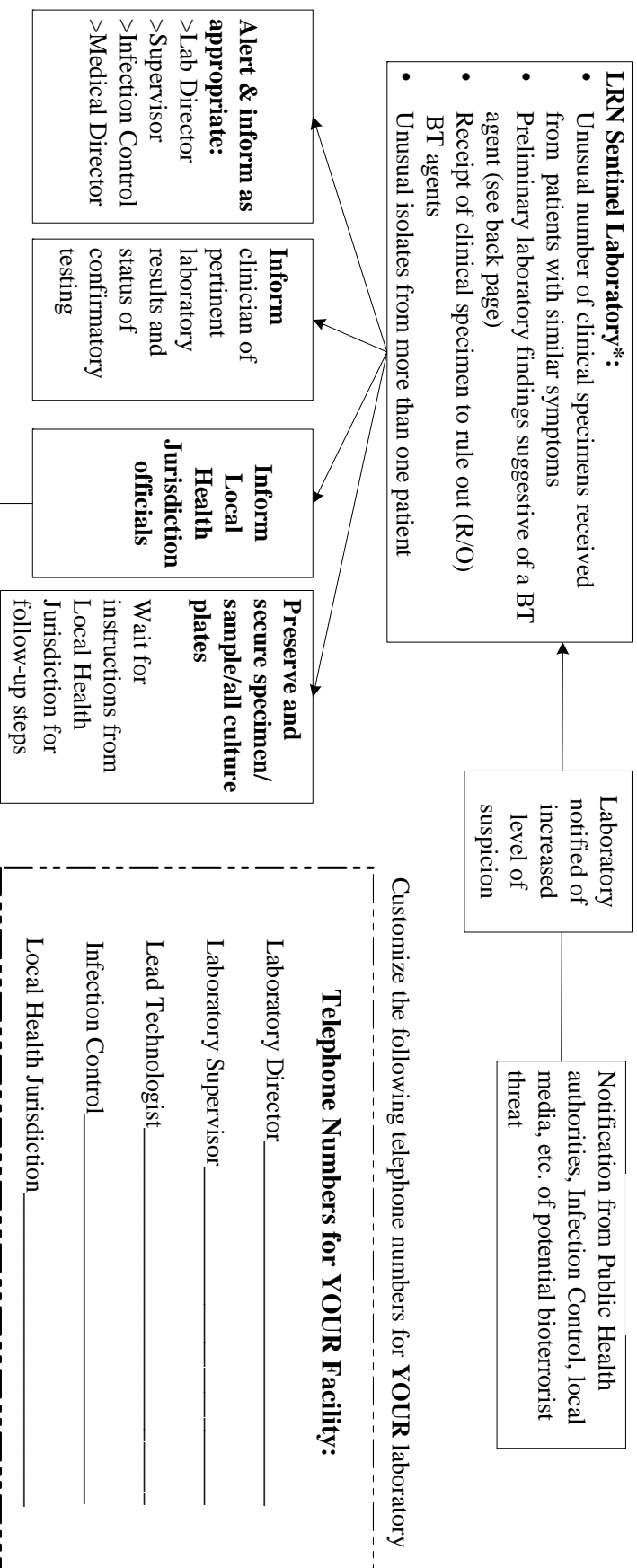
Washington State Clinical Laboratory Advisory Council

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Covert Event

Overt Event



* **LRN Sentinel Laboratory:** Laboratories that perform Blood and/or CSF cultures to RULE OUT a BT agent.

** **LRN Reference Laboratory:** Laboratories specifically authorized by the Centers for Disease Control and Prevention to perform testing to RULE IN the BT agent.

ENVIRONMENTAL SAMPLES: DO NOT ACCEPT any type of non-clinical specimen such as powders, other suspicious substances, or packages. Contact your Local Health Jurisdiction. REFER all phone calls from people regarding environmental specimens to local law enforcement or to your local health jurisdiction.

LRN SENTINEL LABORATORY REFERENCE TABLE

Agent	Culture Methods	Incubation Methods	Recovery Time	Colonial Morphology	Gram Stain Morphology	Preliminary Identification Tests	Action
<i>Bacillus anthracis</i> From: vesicle, sputum, CSF, blood, stool, rectal swab	Blood, Chocolate agar No growth on Mac	35°C in ambient air or CO ₂	8-24 hours	Non-hemolytic, gray colonies with ground glass appearance which "peaks" when touched	Large gram positive rods, oval, sub-terminal spores, no swelling of cell., capsules may be seen from specimen Gram stained	Catalase—positive Motility—negative	Refer to Laboratory designated by the local health jurisdiction
<i>Francisella tularensis</i> From: Blood, tissue, sputum, lymph nodes	Chocolate, BCYE, Thioglycollate, and Thayer-Martin agar Poor growth on BA No growth on Mac	35°C in CO ₂	~24-48 hours Hold up to 10 days	Very small, blue/gray colonies	Tiny gram negative coccobacilli poorly staining	Catalase—negative or weakly positive Oxidase—negative Urea—negative Motility—negative XV strip—no satelliting	Refer to Laboratory designated by the local health jurisdiction
<i>Yersinia pestis</i> From: Lymph node, blood, spleen, liver, sputum, bubo	Grows on routine culture media	22-28°C in ambient air or CO ₂	Grows slowly, 24-48 hours	Small, fried egg colonies may look like beaten copper	Gram negative rods which may show bi-polar staining	Catalase—positive Oxidase—negative Urea—negative Motility—negative TSI—weak acid slant, no change in butt	Refer to Laboratory designated by the local health jurisdiction
<i>Brucella</i> sp. From: Blood, bone marrow, tissue, CSF	Blood, Chocolate, Thayer-Martin or BCYE agar Some strains grow on Mac	35°C in CO ₂	Normally 24-72 hours, may take up to 30 days	Small, gray/white colonies, punctate	Small gram negative cocci-bacilli, poorly staining	Catalase—positive Oxidase—positive Urease—positive XV—negative	Refer to Laboratory designated by the local health jurisdiction
<i>Clostridium botulinum</i> From: Feces, tissue, wound exudates, gastric contents	Blood or brucella agar Chopped meat Broth	Anaerobic incubation at 35°C	24-30 hours	Beta hemolytic with rhizoid colonies on moisture-free media; always swarms on damp media	Gram positive rods with oval, sub-terminal spores which swells the cell	Catalase—negative Indole—negative	Refer to Laboratory designated by the local health jurisdiction
<i>Burkholderia pseudomallei</i> & <i>mallei</i> From: Blood, sputum, wounds	Grows on routine culture media, strongly lactose + on Mac	35°C in ambient or CO ₂	24 hours <i>B. mallei</i> grows more slowly	Creamy tan to orange wrinkled colonies when old, fresh isolate may look like mercury	Gram negative rods similar to Pseudomonas	Catalase—positive Oxidase—positive <i>B. mallei</i> - var. oxidase/non-motile	Refer to Laboratory designated by the local health jurisdiction

References:

1. **Basic Diagnostic Testing Protocols for Level A Laboratories** (updated: December 18, 2002). Centers for Disease Control and Prevention, American Society for Microbiology, and the Association of Public Health Laboratories.
2. **Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response**. CDC MMWR Volume 49/No.RR-4, April 21, 2001.
3. **Manual of Clinical Microbiology**, 7th ed., American Society for Microbiology, 1999, Patrick R. Murray, editor-in-chief.
4. **USAMRIID's Medical Management of Biological Casualties, Handbook 4th ed.** February, 2001 – Appendix E.

12th Annual Clinical Laboratory Conference

November 7, 2005
8:00 a.m. - 4:30 p.m.

Seattle Marriott Hotel at SeaTac
International Airport

If you have not received your Conference Registration
Flyer, contact Leonard Kargacin:

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The program is also available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm

Calendar of Events

PHL Training Classes:

(<http://www.doh.wa.gov/EHSPHL/PHL/train.htm>)

A Basic Course in Urine Sediments

October 19	Shoreline OR
October 20	Shoreline

Northwest Medical Laboratory Symposium

October 26-29, 2005 Seattle

12th Annual Clinical Laboratory Conference

November 7, 2005 Seattle

2006 WSSCLS/NWSSAMT Spring Meeting

April 20-22, 2006 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.